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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,489	04/30/2001	David Bach	20816/2	2352

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,489

Applicant(s)

BACH ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

Applicant fails to provide the complete information for the cited references in page 14.

- (1) *Micro-Array technical articles, Nature Genetics Supplement, Vol. 21, Jan. 1999*- missing authors and page number
- (2) *N. Witowski, "Technology Workshop on Genomic Micro-arrays," Mar. 21-22, 2000*- missing location of the workshop and the page number.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18, 27, 29-35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 18, "said detector detects fluorescence emitted from said depletion area and which travels through said waveguide *at an angle greater* than that which would result in coupling of said fluorescence with said waveguide," is vague and confusing. It is not clear the fluorescence travels through said waveguide greater than what angle which would result in coupling of said fluorescence with said waveguide.

With respect to claims 30-31, the phrase "having a *long* wavelength for heating or light" is vague and indefinite. It is unclear how long the wavelength must be to be considered a long wavelength.

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With respect to claims 27, 34, 35 and 37, it is vague and unclear as to what constitute the claimed "protective layer." Do the applicants mean a cladding layer or a polymer waveguide, or commercial glass or silicon layer?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 (a) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by Feldstein et al. (J. Biomedical. Microdevices, (1999) 1:139-153).

Feldstein et al. anticipate the instant claim by teaching a reaction matrix comprising a waveguide and a cladding layer on the surface of the waveguide. The cladding layer having flow cells channel (depletion areas) where a substance is placed within and can be illuminated by the evanescent wave of light. (page 144; Figure 2 and Figure 6) Feldstein et al. also teach that the refractive index of the surrounding medium must be of a lower refractive index than the waveguide in order to achieve total internal reflection (TIR) for propagation of light. (page 140, left Column, first paragraph) Therefore, Feldstein et al. anticipate the instant claims 1 and 36.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-6, 12-13, 17-20, 22-25, 27-29 and 30-31 are rejected under 35 U.S.C. 103 (a) as unpatentable over Feldstein et al. in view of Booth et al. (USP 5402514).

With respect to claim 2 and 22-25, Feldstein et al. teach using cladding layer couple with waveguide in optical communication with the tested sample. However, Feldstein does not teach using a polymer waveguides. Booth teaches how to make a polymer film waveguide to provide advantages of more homogenous, clearer and distinct boundaries of waveguide (Col. 2, line 60-69; Col. 3, line 30-40; Col. 17, line 31-40) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Feldstein et al. with the polymer waveguides as taught by Booth as an alternative, in order to efficiently detect the presence of a target substance in a sample.

With respect to claims 3-6, 17-20, Feldstein et al. teach coating the binding partner, i.e. antibodies, on the waveguide, contacting the samples with the coated areas and using evanescent wave to excite samples for detection of fluorescence signal change. (Figures 1, 2 and 9) Feldstein et al. also teach placing detector generally in orthogonal to the waveguide. (Figure 7)

With respect to claim 12 and 13, Feldstein et al. teach using CCD imaging array detector to detect fluorescence signal and the CCD detector is placed orthogonal to the waveguide. (Figure 7)

With respect to claims 27 and 29, Feldstein et al. review the important role of refractive index in propagation of light in waveguide by the evanescent wave. It is a well-known

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knowledge in the art that the refractive index of the surrounding medium must be of a lower refractive index, i.e. *different*, than the waveguide in order to achieve total internal reflection (TIR). (page 140, left Col. first paragraph) Feldstein et al. also review the benefits of adding reflective cladding layer to the detection waveguide, such as eliminating the problems of loss of excitation intensity and excess scattered light. (page 144, left Col. Second paragraph)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Feldstein et al. with the factors mentioned above since it is a routine consideration in the art. With respect to add extra intermediate cladding layer, it would have been an obvious to one of ordinary skill in the art at the time the invention was made to incorporate a duplicate design of the recited cladding layer, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. See *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

With respect to claim 28, Feldstein et al. teach automated fluidics device for the array analysis (page 143).

With respect to claims 30-31, Feldstein et al. disclose light source having a wavelength capable of exciting fluorescent molecules for immunoassay. (Figure 6A)

7. Claims 32-35 are rejected under 35 U.S.C. 103 (a) as unpatentable over Feldstein et al. in view of Booth et al, as applied to claims 2, 27, 31 and further in view of Herron et al. (USP 6222619)

With respect to claim 32-35, Feldstein et al reference has been discussed above but is silent to various factors for designing waveguides for detection purpose. Herron et al. review factors of concerning the angle of total internal reflection of the light source entering the waveguides, the depth that the evanescent wave penetrating the depletion area and the thickness of the waveguide, materials for protective layer and the cladding layer chosen, are essential for designing the waveguide-related detection apparatus. (Figure 9) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided

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the reference of Feldstein et al. with the teachings of Herron et al. since all the aforementioned factors taught by Herron et al. are required in the art to achieve an optimal results for the intended detection purpose.

8. Claims 14-16 are rejected under 35 U.S.C. 103 (a) as unpatentable over Feldstein in view of Booth et al, as applied to claims 2 and 3, and further in view of Delamarche et al. (Science (1997) 276: 779-781).

Feldstein et al. teach using multiple channels, i.e. tubings, transporting samples in contact with waveguides. However, Feldstein et al. do not explicitly teach using capillary channel for conveying samples. Delamarche et al. teach a "*simple, inexpensive and economical of reagents*" way in using waveguide techniques to detect *nanoliter* quantities of materials by coupling a plurality of 100 capillary channels. (pages 779 and 781) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Feldstein et al. with capillaries as taught by Delamarche et al., in order to analyze multiple samples for less cost and more efficiently.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldstein et al. in view of Booth et al and Delamarche et al., as applied to claims 2, 3 and 14 above, and further in view of Liu (USP 5444807).

Feldstein et al., Booth et al. and Delamarche et al. references have been discussed *supra* but are silent to the teaching of a microseparation column. It is a well-known knowledge in the art to have microseparation prior to analyze target substance, i.e. coupling HPLC to samples for more purity. Liu teaches improving fluorescence sensitivity using a microseparation HPLC detector for detecting analyte in the fluid. (Col. 4, line 17-21; Col 5, line 36-45) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide modified device of Feldstein with the microseparation column as taught by Liu, in order to improve the sensitivity of the detection.

10. Claim 37 is rejected under 35 U.S.C. 103 (a) as unpatentable over Feldstein et al..

Feldstein et al reference has been discussed but fails to specifically teach adding a intermediate protective layers with the lower refractive index compared to the surrounding layers. Nevertheless, Feldstein teaches the benefits of adding cladding layers, for better results and implicitly for protection of the samples. (page 144, left Column, second paragraph) Therefore, it would have been obvious to one of ordinary skill in the art would place cladding layer(s) having a lesser degree of refractive index than that of the surrounding waveguides since the lower refractive index is a necessary element for allowance of the propagation of light.

11. Claims 7-11 and 21 are rejected under 35 U.S.C. 103(a) as unpatentable over Feldstein et al. in view of Booth et al. and Delamarche et al..

Feldstein et al. teach coupling a cladding layer over six waveguides in detection multiple analytes conveyed by microfluidics. (Figures 2 and 6) However, Feldstein et al. do not teach using polymer waveguides. In addition, Feldstein et al. do not teach designing the sample wells containing a volume less than about 50 nanoliters (10^{-9} L). Booth et al. reveal the advantages of using polymer film waveguides for analyte detection and teach how one in the art makes the polymer waveguides. Delamarche et al. teach applying waveguide techniques for detection of nanoliter quantities of samples in a less-cost and less-complicated fashion by using a plurality of capillaries for sample delivering and detection. (page 779) Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Feldstein et al. with polymer waveguides, as an alternative as taught by Booth, in combination with plurality of nanoliter wells as taught by Delamarche et al., in order to efficiently and economically conduct a multiple array of analytes in a tested sample.

Conclusion

12. No claim is allowed.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641



February 3, 2003



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02/10/03